



UNITED STATES PATENT AND TRADEMARK OFFICE

[Handwritten signature]

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,053	04/03/2002	Timothy James Jegla	18510-002030US	3563

20350 7590 07/15/2004

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,053	Applicant(s) JEGLA ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-13, 15, 23, and 24, drawn to a nucleic acid, a vector, and a host cell,
- II. Claim 14, drawn to a method of detecting a nucleic acid,
- III. Claims 16-21, drawn to polypeptides.
- IV. Claim 22, drawn to an antibody.
- V. Claims 25-32 and 49-56, drawn to a method for identifying a compound that increases or decreases ion flux through a potassium channel.
- VI. Claims 33-35 (in part), drawn to a method of detecting the presence of BK beta 2 in a sample, comprising using BK beta 2-specific antibodies.
- VII. Claims 33-35 (in part), drawn to a method of detecting the presence of BK beta 2 in a sample, comprising using BK beta 2-specific oligonucleotide primers or nucleic acid probes.
- VIII. Claims 36-38 (in part), drawn to a method of detecting the presence of BK beta 3 in a sample, comprising using BK beta 3-specific antibodies.

Art Unit: 1646

- IX. Claims 36-38 (in part), drawn to a method of detecting the presence of BK beta 3 in a sample, comprising using BK beta 3-specific oligonucleotide primers or nucleic acid probes.
 - X. Claims 39-41 (in part), drawn to a method of detecting the presence of BK beta 4 in a sample, comprising using BK beta 4-specific antibodies.
 - XI. Claims 39-41 (in part), drawn to a method of detecting the presence of BK beta 4 in a sample, comprising using BK beta 4-specific oligonucleotide primers or nucleic acid probes.
 - XII. Claim 42, drawn to a method for identifying a compound that increases or decreases ion flux through a potassium channel comprising using a computer system.
 - XIII. Claims 43 and 44, drawn to a method of screening for mutations of a human BK beta gene in a computer system.
 - XIV. Claims 45-48, drawn to a method for identifying a three-dimensional structure of BK beta subunit in a computer system.
2. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIV appears to be the nucleic acid encoding a beta subunit polypeptide of a potassium channel. However, Uebele et al (WO 01/05828 A1, January 25, 2001; priority date July 20, 1999) teach an isolated

Art Unit: 1646

nucleic acid encoding a beta potassium channel that is 100% identical to SEQ ID NO: 1 (see attached sequence alignment).

Therefore, the technical feature linking the inventions of Groups I-XIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

3. The special technical features in Groups I, III, and IV are a nucleic acid, a polypeptide, and an antibody, respectively; whereas the special technical features in Groups II, V-XIV are detecting a nucleic acid, identifying a compound that increases or decreases ion flux through a potassium channel, detecting the presence of BK beta 2, BK beta 3, or BK beta 4 in a sample, comprising using BK beta-specific antibodies or BK beta-specific oligonucleotide primers or nucleic acid probes, identifying a compound that increases or decreases ion flux through a potassium channel comprising using a computer system, screening for mutations of a human BK beta gene in a computer system, and identifying a three-dimensional structure of BK beta subunit in a computer system, respectively.
4. Accordingly, Groups I-XIV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.
5. Furthermore, this application contains claims directed to the following amino acid/nucleic acid sequences and each amino acid/nucleic acid sequence represents an *additional* invention group:

- (i). amino acid sequences set forth in SEQ ID NOS: 1, 3 and 5;

(ii). nucleic acid sequences set forth in SEQ ID NOS: 2, 4, and 6.

According to PCT rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT administrative Instructions, all alternatives of a Markush Group must have a common structure. The amino acid/nucleic acid sequences are not regarded as being of similar nature because all the nucleic acid/amino acid sequences do not appear to share a common structure.

Applicant is advised that a reply to this requirement must include an identification of an amino acid/ nucleic acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. **The Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.**

6. This application also contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: the primers as listed in claim 8 and represented by SEQ ID NOS.

Should Applicants elect Invention I, Applicant is required, in reply to this action, to elect a pair of primers to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that

Art Unit: 1646

a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claim 8 reads on the primers.

The following claim is generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each primer is a distinct chemical entity and has a distinct structure from the others.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

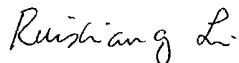
Art Unit: 1646

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Brenda.Brumback@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Ruixiang Li, Ph.D.
Examiner
July 12, 2004